DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m3874n

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

JUN 9 2000

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

Samir Patel, President
Oxy-Health Corporation
9926 Pioneer Boulevard #104
Santa Fe Springs, CA 90670

W/L 59-00

Dear Mr. Patel:

During an inspection of your firm located in Santa Fe Springs, California, on April 19 and 24, 2000, our Investigator determined that your firm manufactures hyperbaric chambers. Hyper-Oxy portable hyperbaric chambers are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act.

Our inspection disclosed that these devices are adulterated within the meaning of Section 510(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, and storage are not in conformance with the Good Manufacturing Practice (GMP) requirements for the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and maintain a device master record for the Hyper-Oxy portable hyperbaric chamber that includes a compilation of records containing procedures and specifications for the finished device [21 CFR 820.181].

2. Failure to maintain device history records for Hyper-Oxy portable hyperbaric chambers to demonstrate that the devices are manufactured in accordance with the device master record [21 CFR 820.184].

3. Failure to establish and maintain procedures for finished device acceptance to ensure that each finished device meets acceptance criteria [21 CFR 820.80(d)].

4. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit [21 CFR 820.198].

5. Failure to establish and maintain procedures to control all documents that are required by the Quality System Regulation [21 CFR 820. 40].

6. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements [21 CFR 820.50].

Additionally, these devices are misbranded within the meaning of Section 510(o) in that the devices were manufactured, prepared or processed in an establishment not duly registered under Section 510 and was not included in a list required by Section 510(j).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Exportability will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Please submit your response to:

Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445

Sincerely,

Thomas L. Sawyer
Acting District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Chief, Food and Drug Branch
601 North 7th Street, MS-357
Sacramento, CA 94234-7320

Peter Lewis, President
Hyperbaric Technologies Inc.,
One Sam Stratton Road, PO Box 69
Amsterdam, NY 12010